

## REMARKS:

Claims 1-28 were filed in the original application, and new claim 29 was added by the Preliminary Amendment filed on 10/12/05 and subsequently entered by the Examiner. Claims 1-13, 16-17, 19, 21-26, and 28-29 have been cancelled, while claims 14 and 27 have been amended. Hence, claims 14, 15, 18, 20, and 27 currently are pending.

Claims 14-29 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. In particular, the term "substantially" was deemed to be indefinite. Claim 14, as presently amended, no longer recites the term "substantially." Accordingly, this rejection has been obviated.

Claims 14-20 were rejected under 35 U.S.C. 103(a) as unpatentable over Langford (U.S. Patent No. 5,443,801; hereinafter the '801 patent) in view of Hichems et al. (U.S. Patent No. 6,468,953). In response, claim 14 has been amended to recite, in pertinent part:

a. applying a chemical sterilizing agent to said- a clean item to achieve high-level disinfection; and

b. providing a final rinse of rinsing the high-level disinfected item with ~~ozone~~ ozonated, filtered water stored in a tank to ~~substantially~~ degrade any remaining chemical residue and biomatter resulting from contamination of said water on or in said disinfected item.

Support for this amendment is found at pages 15 (lines 26-27) to 16 (lines 1-3), which disclose a "treatment with ozonated water is provided by ozonated, filtered water stored in [a] tank. The ozone is continuously added to the water in the tank by re-circulation past the venturi. Thus, the sterility of the water is ensured without exposing the reproprocessor components or items to be cleaned to a constant supply of freshly generated ozone."

As previously stated by the Examiner, the '801 patent does not teach the specific amount of ozone in the water, does not teach the use of a chemical sterilizing agent (such as peracetic acid), and does not teach the specific process steps including treating an item with a chemical sterilizing agent to achieve high-level disinfection as recited by the instant claims. Moreover, in view of the currently amended claim 14, the '801 patent further does not teach providing a final rinse of the high-level disinfected item with ozonated, filtered water stored in a tank or degrading remaining biomatter resulting from contamination of the water. Nor does the Hitchems et al. reference disclose any of the claimed limitations other than the use of a chemical sterilant.

The applicant's provision of a final rinse for degradation of remaining biomatter using filtered, ozonated water stored in a tank is an improvement over the prior art because, as the applicant's numerous articles and declaration of record attest, the problem of persistent contamination is overcome by ensuring the sterility of the water (which can be compromised by the failure of a water filtration system, etc.).

In other words, while one of ordinary skill may have thought to rinse items after a chemical sterilant is used, there is no suggestion or disclosure to rinse the items with filtered, ozonated

water stored in a tank so that biomatter resulting from the contamination of the water (e.g., failure of the water filtration system) can be degraded as recited in claim 14 by the applicant. Thus, the prior art references do not teach or suggest all of the independent claim limitations.

The Examiner also rejected claims 21-29 under 35 U.S.C. 103(a) as unpatentable over WO02/32467; hereinafter the '467 reference). The '467 reference describes disinfecting medical equipment using ozonated water. It does not, however, describe or suggest high-level disinfecting medical equipment and the flushing the sterilizing apparatus components, including a chamber, a filter, a tray, and a fill line, with ozonated water after the completion of the high-level disinfection step. As described above, the inventor discovered that flushing the components of the sterilizing apparatus with sterile water after disinfection of medical equipment ensures that any failure in the water purification or filtration system will not become a source of re-contamination. Because the '467 reference does not describe or show the flushing of a chamber, filter, tray and fill line with ozonated water, persistent contaminants may be harbored and thereby result in re-contamination of the items being processed (as has been highlighted as a continuing problem in the articles submitted in response to the previous Office Action in this case).

In view of the foregoing, as well as the previously submitted objective evidence of unexpected results, long-felt need, failure of others, and skepticism of experts, the applicant respectfully submits that the claims of the present invention are both novel and unobvious in view of the cited art. Therefore, reconsideration of the rejections is respectfully requested.

No fee is believed to have been incurred for this amendment. Should there be any unforeseen costs, please charge our Deposit Account No. 17-0055.

Respectfully submitted,

Quarles & Brady, LLP

A handwritten signature in black ink, appearing to read 'Gavin J. Milczarek-Desai', written in a cursive style.

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